IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

WALTER SHUKER, et al.	:	CIVIL ACTION
	:	
v.	:	No. 13-6158
	:	
SMITH & NEPHEW PLC, et al.	:	

MEMORANDUM

Juan R. Sánchez, J. **March 31, 2015**

Plaintiffs Walter and Vivian Shuker, husband and wife, bring this products liability action against Smith & Nephew, Inc. (S&N) and Smith & Nephew plc (PLC), seeking damages for injuries Walter Shuker sustained after undergoing hip replacement surgery with artificial hip components designed and manufactured by one or both Defendants.[1] Plaintiffs also seek damages for Vivian Shuker's loss of consortium. S&N has filed a motion for summary judgment,[2] asking this Court to grant judgment in its favor as to most of Plaintiffs' claims on the basis that the claims are preempted by the Federal Food Drug and Cosmetic Act (FDCA), as amended by the Medical Device Amendments of 1976 (MDA). Insofar as Plaintiffs assert potentially nonpreempted claims based on Defendants' alleged violations of common-law duties that parallel federal requirements applicable to the hip components in question, S&N asks the Court to dismiss the claims as inadequately pleaded. Plaintiffs oppose S&N's motion and also seek leave to file a Second Amended Complaint. For the reasons set forth below, the Court will grant Plaintiffs' motion for leave to amend and consider Defendants' arguments for summary judgment and/or dismissal as to Plaintiffs' Second Amended Complaint. Because the Court

[1] PLC is the ultimate parent company of S&N. PLC denies that it conducts any business related to medical devices and has moved to dismiss this action for lack of personal jurisdiction. PLC's motion will be addressed by separate order.

[2] While styled as a motion for summary judgment, S&N's motion is actually a motion for summary judgment and/or dismissal.

agrees with S&N that the claims set forth in the Second Amended Complaint are either preempted by the MDA or inadequately pleaded, S&N's motion for summary judgment and/or dismissal will be granted, and Plaintiffs' Second Amended Complaint will be dismissed in its entirety. The Court will, however, grant Plaintiffs leave to amend insofar as they seek to pursue parallel claims based on Defendants' off-label promotion of the hip components at issue.

BACKGROUND[3]

Defendants design and manufacture medical devices for use in hip replacement and hip resurfacing procedures. In a hip replacement, the surgeon covers the patient's hip socket (or acetabulum) with a cup and replaces the ball of the thighbone (the femoral head) with a metal ball attached to a long metal stem, which is inserted into the thighbone. *See* Pls.' Summ. J. Ex. A at 9050, 9052.[4] In a hip resurfacing procedure, the surgeon covers the hip socket with a cup and covers, rather than replaces, the femoral head with a cap. *See id.*

Defendants' hip replacement systems include the R3 Acetabular System (R3 System), which, according to Plaintiffs, consists of four main components: (1) an acetabular shell, (2) a cross-linked polyethylene (or poly) liner, (3) a femoral head, and (4) a femoral stem. *See* Second Am. Compl. ¶ 17. The R3 System is a Class II[5] medical device which the Food and Drug

[3] The following facts are drawn from the allegations of Plaintiffs' Second Amended Complaint and the evidence in the summary judgment record, all of which the Court construes in the light most favorable to Plaintiffs, drawing all reasonable inferences in their favor. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009); *Hugh v. Butler Cnty. Family YMCA*, 418 F.3d 265, 267 (3d Cir. 2005).

[4] Exhibits to Plaintiffs' opposition to S&N's motion for summary judgment are cited herein as "Pls.' Summ. J. Ex. __."

[5] Under the MDA, medical devices are classified in three categories, with different levels of federal oversight, based on the degree of risk they pose to the public. Class I is the lowest risk category; Class III is the highest.

Administration (FDA) has authorized Defendants to market in the United States pursuant to what is known as the § 510(k) process.[6] Under the § 510(k) process, the FDA conducts a "limited form of review" of a new device and may permit the device to be marketed without further regulatory analysis if it determines, based on the manufacturer's submission, that the device is "substantially equivalent" to a preexisting device. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).[7]

Defendants also manufacture the Birmingham Hip Resurfacing (BHR) System, a Class III hip resurfacing system consisting of two main components: (1) a socket in the shape of shallow cup (the acetabular component), which replaces the damaged surface of the hip socket, and (2) a cap in the form of a ball head (the femoral resurfacing component), which covers the

[6] The FDA's authorization with respect to the R3 System is reflected in a series of notifications pertaining to different components of the System. *See* Pls.' Summ. J. Ex. A at 13354-55 (September 12, 2006, notification of § 510(k) authorization for "Smith & Nephew Modular Femoral (Hemi) Heads"); *id.* at 13433-44 (October 17, 2005, notification of § 510(k) authorization for "ANTHOLOGY Hip Stem"); Rouss Decl. Ex. F (June 6, 2007, notification of § 510(k) authorization for "Smith and Nephew REFLECTION 3"). There is no single 510(k) notification covering all four components Plaintiffs identify as part of the R3 System, and S&N's "510(k) Summary" for the System describes it as consisting only of "Acetabular shells and liners." Rouss Decl. Ex. G. Nevertheless, the Court assumes, for purposes of this Memorandum, that the R3 System consists of all of the components identified by Plaintiffs. *See* Pls.' Summ. J. Ex. A at 10002 (PMA supplement excerpt for the Birmingham Hip Resurfacing System describing a Smith and Nephew "total hip replacement system . . . consisting of the R3 Acetabular Shell, poly liner, femoral stem and femoral head" as a Class II device); *id.* at 12535 (March 2012 FDA email suggesting the agency's § 510(k) review of S&N's "R3 XLPE Acetabular Liners" includes review of the compatible femoral heads and stems that are part of the same hip system).

[7] Class I and Class II devices are subject to the § 510(k) process. *See Lohr*, 518 U.S. at 478. Class III devices are generally subject to the separate premarket approval process, described in greater detail below, but a Class III device may enter the market via the § 510(k) process if the FDA finds it is substantially equivalent to a grandfathered device, i.e., a device already on the market before the MDA's effective date and permitted to remain on the market until the FDA promulgates a regulation requiring premarket approval. *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008).

femoral head. *See* Pls.' Summ. J. Ex. A at 9050-51; Rouss Decl. ¶ 5. The cap has a small stem that is inserted into the top of the thighbone. *See* Pls.' Summ. J. Ex. A at 9051. Both the acetabular component and the femoral resurfacing component of the BHR system are made of metal; hence, the System is referred to as having a metal-on-metal coupling or articulation. In contrast to the R3 System, which entered the market via the § 510(k) process, the BHR System underwent the substantially more rigorous premarket approval (PMA) process, whereby approval is granted only if FDA finds, after reviewing the manufacturer's voluminous application materials, that "there is a 'reasonable assurance' of the device's 'safety and effectiveness.'"[8] *See Riegel v. Medtronic, Inc.*, 552 U.S. 312 317-18 (2008) (quoting 21 U.S.C. § 360e(d)). The FDA

[8] To obtain premarket approval, a manufacturer must submit to the FDA "what is typically a multivolume application," including, inter alia,

> full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a full statement of the device's components, ingredients, and properties and of the principle or principles of operation; a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device; samples or device components required by the FDA; and a specimen of the proposed labeling.

Riegel, 552 U.S. at 317-18 (citation and internal quotation marks omitted). In reviewing a PMA application—a process on which the FDA spends an average of 1,200 hours per application—the agency may request additional data from the manufacturer and may seek input from outside experts. *See id.* As noted, the FDA grants premarket approval "only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness,'" *id.* (quoting 21 U.S.C. § 360e(d)), after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," *id.* (quoting 21 U.S.C. § 360c(a)(2)(C)). Once premarket approval is granted, "the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319.

granted Defendants'[9] application for premarket approval of the BHR system in May 2006. Rouss Decl. Ex. A.

The following year, in April 2007, Defendants filed a PMA application supplement, seeking approval for a line extension to the BHR System consisting of a modular version of the BHR cup. Rouss Decl. ¶ 6 & Exs. B & C. The modular BHR cups, referred to as R3 Metal on Metal Cups, consist of an R3 acetabular shell made of titanium alloy and an R3 metal liner made of cobalt-chromium alloy. Rouss Decl. Ex. C. The PMA supplement represented that the metal-on-metal articulation of the BHR System with the modular cups would be unchanged from that of the System with the one-piece cups the FDA had previously approved. *See id.*; Pls.' Ex. A at 9999. On November 13, 2008, the FDA approved the PMA supplement and granted Defendants permission to distribute the BHR System with the modular cups. Rouss Decl. Ex. B. The FDA also approved labeling[10] associated with the line extension, including a surgical technique addendum covering use of the modular R3 Metal on Metal Cups within the BHR System. Rouss Decl. ¶ 8 & Ex. D. The surgical technique addendum specifically notes that "in the US, the R3 metal liner is intended for use as part of the BHR system only," cautioning that if the resurfacing procedure is abandoned "in favor of a total hip replacement, the R3 acetabular shell must be used with a mating R3 poly liner." Rouss Decl. Ex. D at 12157, 12159. The addendum also cautions that if, post-operatively, "the BHR resurfacing head must be revised to a total hip arthroplasty [i.e., replacement], . . . the R3 acetabular shell can remain in place if well-fixed," but "the R3

[9] The Court notes that the FDA directed its notification that the BHR System had received premarket approval to "Smith & Nephew Orthopaedics" at the same Memphis, Tennessee, address where S&N is located. *See* Rouss Decl. Ex. A.

[10] For purposes of the FDCA, the term labeling means "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m).

metal liner must be replaced with an R3 poly liner, which can be used with any compatible legally marketed Smith & Nephew femoral stem and mating ceramic or metal femoral head component." *Id.* at 12159.

In February 2009, four months after the R3 Metal on Metal Cup received premarket approval as part of the BHR System, S&N issued a press release announcing "the introduction of a metal liner option for its R3 Acetabular System, an advanced multi-bearing cup system used in hip replacement and resurfacing procedures." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A;[11] *see also* Second Am. Compl. ¶ 91. The press release noted the FDA had recently approved the metal liner for use with the BHR System, but said nothing about the regulatory status of the liner for use in total hip replacements.[12] S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A. The press release touted the R3 System's unique capacity to "accommodate[] the major advanced bearing options, including metal-on-metal, ceramic-on-ceramic, cobalt chrome on cross-linked polyethylene (XLPE), and the company's exclusive OXINIUM™ Oxidized Zirconium on XLPE," and described the R3 System's multi-bearing cup as providing "intraoperative flexibility for surgeons" and "solutions designed to reduce wear and the subsequent need for revision surgery." *Id.*

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[11] Although the Second Amended Complaint quotes from the press release, the press release is not included as an exhibit to the Complaint, nor is it part of the summary judgment record. S&N has produced a copy of the press release as an exhibit to its opposition to Plaintiffs' motion for leave to amend. Because Plaintiffs' claims are based on the press release, the Court may properly consider it, even in evaluating the sufficiency of Plaintiffs' claims. *See Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007) (holding a court may consider "documents incorporated into the court by reference" in evaluating a motion to dismiss).

[12] Defendants did not seek FDA approval to use the R3 optional metal liner with the R3 System. *See* Second Am. Compl. ¶ 96. Outside the United States, however, the liner received regulatory approval for use in a total hip replacement. *See* S&N's Opp'n to Pls.' Mot. for Leave to Amend 9 & Ex. C.

On April 29, 2009, Walter Shuker underwent right total hip replacement surgery in which his surgeon, Kevin Terefenko, M.D., implanted the following components manufactured by Defendants: (1) a modular femoral head made of cobalt-chrome, (2) a modular head sleeve made of cobalt-chrome, (3) a femoral stem component, (4) an R3 no-hole hemispherical acetabular shell, and (5) an R3 acetabular liner made of cobalt-chrome, i.e., an R3 metal liner. Pls.' Summ. J. Ex. C at 2; Pls.' Summ. J. Ex. E. The first four components used in Mr. Shuker's hip replacement surgery were cleared by the FDA pursuant to the § 510(k) process.[13] The R3 metal liner component, however, did not receive FDA § 510(k) clearance as part of the R3 System. Rather, the metal liner was part of the R3 Metal on Metal Cup that received premarket approval as part of the BHR System. *See* Rouss Decl. ¶ 9; *compare* Pls.' Summ. J. Ex. E (chart-stik labels), *with* Rouss Decl. Ex. D at 12161 (catalog numbers for R3 metal liners). The FDA did not approve the R3 metal liner for use with the R3 System in a total hip replacement procedure. Dr. Terefenko's use of the metal liner component in Mr. Shuker's surgery was thus an "off-label" use, i.e., a use for a purpose other than "that for which it has been approved by the FDA." *See Buckman Co. v. Pls.' Legal Comm.*, 531 U.S. 341, 350 (2001).

Approximately 21 months after his surgery, Mr. Shuker began developing increasing pain and discomfort in his buttocks, groin, and thigh, limiting his daily activities. Second Am. Compl. ¶ 110. On May 23, 2011, he underwent an aspiration procedure, performed by Dr.

[13] *Compare* Pls.' Summ. J. Ex. E (chart-stik labels showing catalog numbers for components used in Mr. Shuker's surgery), *with* Pls.' Summ. J. Ex. A at 13354-55, 13361, 13433-34, 13466 (§ 510(k) notifications and catalog numbers for femoral head, head sleeve, and femoral stem component), *id.* at 12188, 13178 (catalog numbers for R3 no-hole acetabular shell), *and* Rouss Decl. Ex. F (§ 510(k) notification for acetabular shell). The R3 acetabular shell used in Mr. Shuker's surgery also appears to have received premarket approval as part of the BHR System. *See* Rouss Decl. ¶ 9; *compare* Pls.' Summ. J. Ex. E (chart-stik labels), *with* Rouss Decl. Ex. D at 12161 (catalog numbers for R3 no-hole acetabular shell component of the R3 modular resurfacing acetabular cup, i.e., the R3 Metal on Metal Cup).

Terefenko, during which a milky brown tinged fluid and metallic debris were removed from his body. *Id.* ¶ 111. Dr. Terefenko determined Mr. Shuker's pain was caused by metal sensitivity due to the degeneration of the metal-on-metal articulation of his artificial hip and decided that replacement of the metal-on-metal articulation was necessary to relieve the pain. *Id.* On July 6, 2011, Mr. Shuker underwent a further hip surgery during which Dr. Terefenko replaced the existing metal-on-metal articulation with an Oxinium head and a polyethylene liner. *Id.* ¶ 112. After the surgery, Mr. Shuker again developed extreme pain in his right hip. *Id.* ¶ 113. Dr. Terefenko performed a second aspiration procedure on November 12, 2012, and determined that Mr. Shuker had developed an infection at the surgery site. *Id.* In December 2012 and January 2013, Mr. Shuker underwent further surgeries to remove and replace the R3 System. *Id.* ¶¶ 114-15.

In June 2012, almost a year after Mr. Shuker's surgery to replace the metal-on-metal articulation of the components originally implanted, Defendants announced they had "chosen to withdraw the optional metal liner component within the R3 Acetabular System." *Id.* ¶ 99; *see also* Pls.' Summ. J. Ex. A at 13963. Defendants explained the withdrawal was a "precautionary measure" based on data from sources including "Australian and [United Kingdom] patient registries," which indicated the metal liner component within the R3 System was not performing as well as the company would like. Second Am. Compl. ¶ 100. That same month, the Medicines and Healthcare Products Regulatory Agency (MHRA), the analogue of the FDA in the United Kingdom, advised surgeons to stop using the R3 metal liner because of the higher revision rates associated with it than with nonmetal liners.[14] *Id.* ¶ 102. The MHRA also advised surgeons to

[14] The MHRA reported the revision rate for the R3 metal liner was 6.4% at four years, which not only was higher than the revision rate for nonmetal liners, but also exceeded the "4% guidance figure at four years from National Institute of Health and Clinical Excellence." *Id.* ¶ 102.

annually monitor those patients who had been fitted with the metal liners to ensure that "any complications such as pain or swelling [would be] picked up and treated early." *Id.* At the time of the withdrawal, a majority of the R3 metal liners in use globally had been used in hip replacement, rather than resurfacing, procedures. *See* Pls.' Summ. J. Ex. A at 13693.

In September 2013, Plaintiffs commenced the above-captioned action by filing a Complaint in the Court of Common Pleas of Philadelphia County. S&N removed the case to federal court the following month and, after answering the Complaint, filed a motion for judgment on the pleadings. Following a Rule 16 conference at which Plaintiffs indicated their desire to amend their Complaint, the Court granted Plaintiffs leave to amend and denied S&N's motion for judgment on the pleadings without prejudice.

In December 2013, Plaintiffs filed their First Amended Complaint, asserting claims for negligence/negligence per se, negligence based on violations of various FDA regulations, strict products liability, breach of express warranty, breach of implied warranties of merchantability, fraud, and loss of consortium. S&N thereafter filed a motion to dismiss, arguing Plaintiffs' claims were expressly preempted by the preemption provision of the MDA, 21 U.S.C. § 360k, and were inadequately pleaded insofar as Plaintiffs attempted to assert a nonpreempted negligence claim premised on violations of FDA regulations. S&N's preemption argument was based on the assertion that the R3 metal liner used in Mr. Shuker's hip replacement surgery received premarket approval, an assertion that Plaintiffs disputed in their First Amended Complaint. Although S&N submitted certain FDA documents in support of its position, this Court found the documents, standing alone, were insufficient to establish the regulatory status of the metal liner used in Mr. Shuker's surgery, and the Court therefore denied the motion to dismiss. Recognizing that the preemption issue was potentially dispositive of most (if not all) of

Plaintiffs' claims, however, the Court amended the scheduling order to permit the parties to take discovery on the preemption issue, following which S&N could to renew its preemption argument in a motion for summary judgment. The Court deferred ruling on the sufficiency of Plaintiffs' parallel claim pending the re-briefing of the preemption issue.

S&N has now renewed its preemption argument on summary judgment, asserting Plaintiffs' claims are preempted and their attempt to plead a nonpreempted parallel claim remains unavailing. After S&N filed its summary judgment motion, Plaintiffs filed a motion for leave to file a Second Amended Complaint to clarify the regulatory history and status of the artificial hip implanted in Mr. Shuker, to refine causes of action based on Defendants' active promotion of off-label uses of their products, and to clarify their parallel claims.

APPLICABLE LEGAL STANDARDS

S&N seeks summary judgment as to most of Plaintiffs' claims on the ground that the claims are preempted. Under Federal Rule of Civil Procedure 56, summary judgment shall be granted "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Material facts are those facts "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A factual dispute is genuine if "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Id.* "Where the record taken as a whole could not lead a rational trier of fact to find for the non-moving party, there is no 'genuine issue for trial.'" *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citation omitted).

S&N also seeks dismissal of any nonpreempted claims based on Defendants' alleged violation of common-law duties that parallel federal requirements on the ground that such claims

are inadequately pleaded and thus fail to state a claim on which relief can be granted. To withstand a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6), "a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the facts pleaded "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Id.* In evaluating a Rule 12(b)(6) motion, a district court first must separate the legal and factual elements of the plaintiff's claims. *See Fowler v. UPMC Shadyside*, 578 F.3d 203, 210 (3d Cir. 2009). The court "must accept all of the complaint's well-pleaded facts as true, but may disregard any legal conclusions." *Id.* at 210-11. The court must then "determine whether the facts alleged in the complaint are sufficient to show that the plaintiff has a 'plausible claim for relief.'" *Id.* at 211 (quoting *Iqbal*, 556 U.S. at 679).

In addition to opposing S&N's motions, Plaintiffs seek leave to file a Second Amended Complaint pursuant to Federal Rule of Civil Procedure 15(a). Rule 15 "embodies a liberal approach to pleading," and leave to amend "must generally be granted unless equitable considerations render it otherwise unjust." *Arthur v. Maersk, Inc.*, 434 F.3d 196, 202, 204 (3d Cir. 2006); *see also* Fed. R. Civ. P. 15(a)(2) (directing that courts "should freely give leave [to amend] when justice so requires"). A district court has discretion to deny a request to amend, however, "if it is apparent from the record that (1) the moving party has demonstrated undue delay, bad faith or dilatory motives, (2) the amendment would be futile, or (3) the amendment would prejudice the other party." *Hill v. City of Scranton*, 411 F.3d 118, 134 (3d Cir. 2005). "An amendment is futile if the amended complaint would not survive a motion to dismiss for

failure to state a claim upon which relief could be granted." *Alvin v. Suzuki*, 227 F.3d 107, 121 (3d Cir. 2000).

DISCUSSION

Plaintiffs' First Amended Complaint is based on the faulty premise that the R3 metal liner was a component of the § 510(k)-cleared R3 System. Discovery has confirmed that the only regulatory approval the R3 metal liner received in the United States is premarket approval as part of the BHR System. In their proposed Second Amended Complaint, Plaintiffs seek to correct their allegations regarding the regulatory status of the metal liner and the other components used in Mr. Shuker's hip replacement surgery, and, in light of these changes, to refine their allegations in support of a nonpreempted parallel claim based on Defendants' alleged violations of federal law. S&N opposes Plaintiffs' motion for leave to amend solely on the basis that permitting the amendment would be futile because the Second Amended Complaint still fails to plead a viable claim. Because the regulatory status of the components implanted in Mr. Shuker is essential to the Court's determination of what claims Plaintiffs can and cannot pursue, and because S&N does not suggest it would be prejudiced by the amendment, the Court will grant Plaintiffs' motion for leave to amend and will consider S&N's arguments for summary judgment and dismissal as to Plaintiffs' Second Amended Complaint.

S&N argues most of Plaintiffs' claims are preempted by the MDA's express preemption provision, which, subject to an exception not applicable here, provides:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. § 360k(a). The Supreme Court has established a two-step analysis for determining whether state tort claims with respect to a medical device are preempted under § 360k(a). "Since the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirement applicable . . . to the device' under federal law," a court must first determine "whether the Federal Government has established requirements applicable to [the device]." *Riegel*, 552 U.S. at 321 (quoting § 360k(a)(1)). If it has, the court must then determine whether the plaintiff's state-law claims "are based upon [state] requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22 (quoting 21 U.S.C. § 360k(a)).

As to the first step in the preemption analysis, the Supreme Court has held "[p]remarket approval . . . imposes 'requirements' under the MDA." *Id.* at 322. Section 510(k) clearance does not. *Id.* In explaining the distinction between the two forms of approval for preemption purposes, the Court noted that whereas § 510(k) is "focused on *equivalence*, not safety," *id.* at 323 (quoting *Lohr*, 518 U.S. at 493), premarket approval "*is* federal safety review" *id.* Moreover, while devices cleared under § 510(k) are subject only to general federal regulations "applicable across the board to almost all medical devices," premarket approval is device-specific. *See id.* at 322-23. Indeed, once premarket approval is granted, the FDA requires the device "to be made with almost no deviations from the specifications in its approval application, for the reason that the FDA has determined that the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323; *see also Horn v. Thoratec Corp.*, 376 F.3d 163, 170-72 (3d Cir. 2004) (holding premarket approval imposes federal requirements on a device and noting the FDA's position that a premarket approval order from the agency "specifically approves as a matter of law those features set forth in the application and binds the

manufacturer to produce and market the product in compliance with the specifications as approved by FDA" (emphasis omitted)). Medical devices that enter the market via the PMA process are thus subject to federal requirements for purposes of § 360k(a).

If a device is subject to federal requirements, § 360k(a) preempts those state requirements "with respect to [the] device" that are "different from, or in addition to," the federal requirements and that "relate[] to the safety and effectiveness of the device." Duties imposed pursuant to state tort law are "requirements" for purposes of the preemption provision, *Riegel*, 552 U.S. at 324; hence, state tort claims relating to the safety and effectiveness of a device are preempted to the extent that the state duties differ from or add to the federal requirements. Section 360k(a) does not, however, "prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," as "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.* at 330. Section 360k(a) thus protects a manufacturer of a PMA-approved medical device from civil liability "to the extent that it has *complied* with federal law, but it does not extend protection from liability where the claim is based on a *violation* of federal law." *Bausch v. Stryker Corp.*, 630 F.3d 546, 552 (7th Cir. 2010).

After discovery, it is now undisputed that the R3 metal liner used in Mr. Shuker's surgery received premarket approval as part of the BHR System, while the rest of the components were cleared pursuant to the § 510(k) process.[15] It is also undisputed that the FDA never approved the particular combination of components implanted in Mr. Shuker for use together as a single device. The parties disagree as to whether and how the MDA's preemption provision applies in

[15] As noted, the R3 acetabular shell appears to have been both PMA-approved and § 510(k)-cleared.

these unusual circumstances in which a physician uses a component from a PMA-approved device off-label with components from a § 510(k)-cleared device.

S&N argues because the liner received premarket approval as part of the BHR System, there are federal requirements applicable to the liner, and Plaintiffs' tort claims, all of which relate to the safety and effectiveness of the liner in some way, are preempted, with the exception of Plaintiffs' claim based on violations of FDA regulations and FDCA provisions.[16] S&N maintains the fact that Dr. Terefenko used the liner off-label with components of a device that was otherwise § 510(k)-cleared does not deprive the liner of the protections of § 360k(a).

Plaintiffs dispute that the R3 metal liner is itself a device subject to federal requirements when used outside of the BHR System. Noting that the FDA approves hip systems, not individual components, Plaintiffs argue the hip system implanted in Mr. Shuker, which consisted predominantly of components from the § 510(k)-cleared R3 System, should be regarded for preemption purposes either as a § 510(k) device or as a new Class III device that has not received either § 510(k) clearance or premarket approval. Either way, Plaintiffs contend that because the device at issue—i.e., the entire hip system Mr. Shuker received—never underwent the PMA process, § 360k(a) is inapplicable. Alternatively, Plaintiffs contend Defendants forfeited the benefits of preemption by promoting the R3 metal liner for use off-label with the R3 System.

Although there is scant case law addressing how the MDA's preemption provision applies with respect to a component of device that has received premarket approval when used independently of the remainder of the device, two federal district courts in New York have considered this question with respect to the same Smith & Nephew components at issue here. *See Bertini v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 246 (E.D.N.Y. 2014); *Simon v. Smith &*

[16] Although S&N does not contend this parallel claim is preempted, it argues the claim should nevertheless be dismissed because it is inadequately pleaded.

Nephew, Inc., 990 F. Supp. 2d 395 (S.D.N.Y. 2013), *reconsideration denied*, 18 F. Supp. 3d 423 (S.D.N.Y. Mar. 26, 2014). Both cases involved plaintiffs who, like Mr. Shuker, had hip replacement surgery in which their surgeons implanted them with the R3 System and the optional R3 metal liner. Both plaintiffs eventually experienced problems with their artificial hips and, after undergoing revision surgery, sued S&N, asserting products liability-related claims, which S&N moved to dismiss as both preempted and inadequately pleaded. With regard to preemption, in both cases, the courts concluded that because the R3 metal liner had received premarket approval as part of the BHR System, claims with respect to the liner were preempted. *See Simon*, 18 F. Supp. 3d at 428; *Bertini*, 8 F. Supp. 3d at 254. The courts rejected the argument that use of the liner outside of the BHR System affected the preemption analysis, noting the question under § 360k(a) "is not whether there are federal requirements applicable to a particular *use* of a device," but "whether there are federal requirements applicable to the *device*." *Simon*, 18 F. Supp. 3d at 428 (quoting *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 779 (D. Minn. 2009) (internal quotation marks omitted)); *see also Bertini*, 8 F. Supp. 3d at 255. While both courts suggested claims relating solely to the § 510(k)-cleared components of the R3 System would not be preempted, they concluded the plaintiffs had not pleaded any nonpreempted claims, as the product defects the plaintiffs identified pertained either to the R3 metal liner itself or to the liner's interface with other components. *See Simon*, 18 F. Supp. 3d at 428-29 (holding whether the plaintiff's injuries were "understood to have resulted from [the R3 metal] liner alone . . . or from use of that liner in combination with other components of the R3 Acetabular System . . . , the metal liner [wa]s at the heart of each and every one of [plaintiff's] claims" and the claims were therefore preempted); *Bertini*, 8 F. Supp. 3d at 255-58.

The Court agrees with the *Simon* and *Bertini* courts that insofar as Plaintiffs' claims challenge the safety and effectiveness of the R3 metal liner, the claims are preempted under § 360k(a). As both of those courts recognized, preemption under § 360k(a) turns on whether there are federal requirements "applicable . . . to the device" and, if so, whether the plaintiff's state tort claims would impose requirements relating to the safety or effectiveness of the device that are "different from, or in addition to," the federal requirements. 21 U.S.C. § 360k(a); *see also Riegel*, 552 U.S. at 321-22. Upon the FDA's approval of Defendants' PMA application for the multi-component BHR System and PMA supplement for the R3 Metal on Metal Cup, Defendants were required to produce and market the device, including all of its constituent components, in accordance with the specifications approved by the FDA. *See Riegel*, 552 U.S. at 323; *Horn*, 376 F.3d at 170-72; *see also* 21 U.S.C. § 321(h) (defining the term "device" to include "any component, part, or accessory" thereof). Thus, under *Riegel*, the FDA's approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the Cup—and on the R3 metal liner, a component of the Cup—for purposes of § 360k(a). *See, e.g.*, *Hawkins v. Medtronic, Inc.*, No. 13-499, 2014 WL 346622, at *5 (E.D. Cal. Jan. 30, 2014) ("The requirements set forth in the premarket approval for the entire device are just as applicable to the components that together form the FDA-approved device as the device itself."); *Eidson v. Medtronic, Inc.* (*Eidson I*), 981 F. Supp. 2d 868, 881 n.3 (N.D. Cal. 2013) (holding premarket approval of a three-component medical device established federal requirements for two components of the device when used without the third).

Plaintiffs argue the fact that the R3 metal liner received premarket approval for use with the BHR System is irrelevant because Dr. Terefenko used it as part of a different hip system, which was not PMA-approved. Citing a statement from an FDA employee that the agency

"review[s] hip systems and not individual components," Pls.' Summ. J. Ex. A at 12535, Plaintiffs argue the Court must look at the hip system implanted in Mr. Shuker as a whole in applying the preemption analysis. While this approach makes sense in cases in which the FDA has actually reviewed the particular system at issue, that is not the case here, as the R3 System the FDA cleared via the § 510(k) process did not include the R3 metal liner. There is thus no basis to characterize the hip system implanted in Mr. Shuker as the § 510(k)-cleared R3 System.

The fact that the FDA never reviewed the particular hip system Mr. Shuker received via either the § 510(k) or the PMA process distinguishes this case from the cases Plaintiffs cite in which courts have held the preemption analysis cannot be applied differently to individual components of a multi-component medical device, but must be applied to the device as a whole. In all of those cases, the device as a whole received premarket approval, generally as a result of the FDA's approval of a PMA supplement permitting the manufacturer to incorporate a component that previously received § 510(k) clearance into a PMA-approved device. In that situation, courts have uniformly rejected the argument that the § 510(k)-cleared component was not subject to express preemption, holding the approval of a PMA supplement incorporating the § 510(k)-cleared component extended premarket approval to the entire device. *See Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 485-88 (W.D. Pa. 2012); *Duggan v. Medtronic, Inc.*, 840 F. Supp. 2d 466, 471-72 (D. Mass. 2012); *Lewkut v. Stryker Corp.*, 724 F. Supp. 2d 648, 656-57 (S.D. Tex. 2010); *see also Bass v. Stryker Corp.*, 669 F.3d 501, 508 & n.1 (5th Cir. 2012) (upholding a district court's finding that an acetabular shell that the plaintiff maintained was not subject to premarket approval testing was part of the PMA-approved hip replacement system at issue). None of these cases involved a device created by a physician's off-label use of a PMA-approved component with components of a § 510(k)-cleared system. If anything, the cases

reinforce the conclusion that approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the R3 metal liner as a component of the Cup.[17]

As Plaintiffs note, the FDA's approval of the R3 metal liner was predicated on Defendants' representations regarding its intended use as part of the BHR System. *See* 21 U.S.C. § 360c(a)(2) (providing that, for purposes of premarket approval, "the safety and effectiveness of a device are to be determined . . . with respect to the persons for whose use the device is represented or intended [and] with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device"); *id.* § 360e(d)(1)(A) (providing that in

[17] In *Huskey v. Ethicon, Inc.*, a case cited by Plaintiffs as supplemental authority, the court applied the converse of the principle applied in the cases cited above, holding that "[j]ust as 'a device receiving premarket approval cannot be separated into its component parts to avoid application of express preemption,' a device receiving 510(k) approval cannot be separated into its component parts to create express preemption." 29 F. Supp. 3d 736, 748 (S.D. W. Va. 2014) (citations omitted). Plaintiffs argue the principle recognized in *Huskey* applies equally here. But this argument overlooks the critical fact that the particular assemblage of components Mr. Shuker received was never cleared as a single device via the § 510(k) process. While it may "make[] no sense" to apply a different preemption analysis to different components of a device the FDA has authorized the manufacturer to market as a single medical device, *see id.* (citation omitted), this case does not involve such a device, and *Huskey* is therefore inapposite.

It also bears mention that the preemption argument the court rejected in *Huskey* was significantly broader than the argument S&N advances in this case. *Huskey* concerned a § 510(k)-cleared medical device called the Gynecare TVT Obturator (or TVT-O), which included a mesh tape, or sling, made of Prolene polypropylene filaments, the same material used in the Prolene suture, a separate, PMA-approved medical device. The manufacturer argued because the suture, which consisted of single Prolene filament, received premarket approval, the plaintiffs' claims that the Prolene filaments in the mesh tended to degrade were preempted. Although the court rejected this argument on the basis that the TVT-O as a whole had been cleared via the § 510(k) process and thus could not be separated into its component parts for purposes of conducting a preemption analysis, the suture was not so much a component of the TVT-O as a device made of the same material. The court thus rejected the notion that the FDA's grant of premarket approval for a device made of a particular material constituted approval of that material for all purposes, explaining, by way of analogy: "If a specific type of metal were approved for use in a bone screw via the premarket approval process, it would not follow that that same type of metal was safe in all medical devices, no matter what their function in the human body." *Id.* at 747 (citation omitted).

The Court also notes that insofar as *Huskey* rejected the analysis in *Simon* and *Bertini*, it did so based at least in part on the faulty assumption that the R3 metal liner was part of the § 510(k)-cleared R3 System. *See id.* at 749.

determining whether to approve or deny a PMA application, "the Secretary shall rely on the conditions of use included in the proposed labeling as the basis for determining whether or not there is a reasonable assurance of safety and effectiveness, if the proposed labeling is neither false nor misleading"). But while the FDA considers the intended use of a device in determining whether to grant premarket approval, the requirements such approval imposes on a device are not use-specific, as the FDA does not regulate the use of medical devices—or their components—by physicians, who remain free to use such devices in an off-label manner. *See, e.g.*, *Ramirez v. Medtronic, Inc.*, 961 F. Supp. 2d 977, 988 (D. Ariz. 2013). In other words, by granting premarket approval, the FDA requires the manufacturer of an approved device to place the device on the market in the form—and accompanied by the warnings and indications for use—approved by the agency, but does not prevent physicians from using the device in a different manner. *See* 21 C.F.R. § 396 (providing "[n]othing in [the FDCA] shall be construed to limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient for any condition or disease within a legitimate health care practitioner-patient relationship"); *Buckman*, 531 U.S. at 350 (recognizing "'off-label' usage of medical devices . . . is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine"). A physician's decision to use a PMA-approved device off-label does not change the manufacturer's obligation to produce and market the device "with almost no deviations from the specifications in its approval application," *Riegel*, 552 U.S. at 323; hence, the mere fact a device is used off-label does not render § 360k(a) inapplicable. *See id.* at 320, 322-23 (holding the premarket approval of a balloon catheter imposed federal requirements on the catheter under the MDA notwithstanding that the plaintiff's physician had used the device in a manner contraindicated by the product

labeling); *Perez v. Nidek Co.*, 711 F.3d 1109, 1118 (9th Cir. 2013) (holding a laser system approved via the PMA process for treating nearsightedness was "subject to device-specific requirements under the PMAs," even when used in surgery to treat farsightedness).[18] As one district court has observed, if the law were otherwise,

> a manufacturer of a medical device could scrupulously adhere to the FDA's every command—and meet every requirement imposed on the design, manufacture, labeling, and marketing of the device—and nevertheless be sued under the tort law of any of the fifty states because a health-care provider, without the manufacturer's consent or even knowledge, decided to put the device to an off-label use.

Riley, 625 F. Supp. 2d at 778.[19]

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[18] This is true whether the physician uses the entire device in an off-label manner or, as here, uses a component of the device off-label with components of a separate device. *See, e.g.*, *Hawkins*, 2014 WL 346622, at *5 (rejecting the argument that a component of a PMA-approved device was not subject to federal requirements when used without the other component of the device, as use of the one component without the other was "simply an off-label use of the device"); *Houston v. Medtronic, Inc.* (*Houston I*), 957 F. Supp. 2d 1166, 1176 (C.D. Cal. 2013) (same).

[19] Plaintiffs argue that even if off-label use of a device does not render § 360k(a) inapplicable when such use was the result of a decision by a physician in which the manufacturer played no part, a different rule applies when the manufacturer actively promotes the off-label use. Citing *Ramirez v. Medtronic, Inc.*, *supra*, Plaintiffs urge the Court to hold Defendants forfeited the protections of § 360k(a) by promoting the R3 metal liner for use off-label with the R3 System. In *Ramirez*, the court recognized a limited exception to § 360k(a) for state-law claims based on off-label promotion. The court distinguished such claims from claims based simply on off-label *use* on the ground that the manufacturer's promotion of an off-label use violates federal law and creates a new intended use of the device for which FDA approval is required. *See* 961 F. Supp. 2d at 990 (citing 21 C.F.R. § 814.39, which requires a manufacturer to submit a PMA supplement to introduce new indications for use of a PMA-approved device). The court observed that allowing the manufacturer to enjoy the protections of § 360k(a) in these circumstances would not serve the statute's purpose to avoid having a state body "arrive at a determination regarding a device's safety that conflicts with the conclusion the FDA made after the rigorous PMA process." *See id.* at 991. The court concluded that absent FDA approval of the new intended use created by the manufacturer's off-label promotion, there "[wa]s nothing to preempt state law requirements." *Id.* at 993.

As an initial matter, because the holding in *Ramirez* is limited to claims based on off-label promotion, the case has no application to most of Plaintiffs' claims, which are not specifically based on allegations that Defendants promoted the R3 metal liner for off-label use.

Having concluded that the FDA's approval of the PMA supplement for the R3 Metal on Metal Cup imposed federal requirements on the R3 metal liner for purposes of § 360k(a), the Court must next determine whether Plaintiffs' state-law claims impose requirements "with respect to" the liner that are "different from, or in addition to" the federal requirements. In their Second Amended Complaint, Plaintiffs assert variations of the same seven counts included in their First Amended Complaint: (1) negligence/negligence per se (Count I), (2) negligence based on violations of FDA regulations and FDCA provisions (Count II), (3) strict products liability (Count III), (4) breach of express warranty (Count IV), (5) breach of implied warranties of

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Off-label promotion is part of both Plaintiffs' fraud claim and their negligence claim based on violations of federal law, but, even under *Ramirez*, § 360k(a) remains applicable to the remaining claims in Plaintiffs' Second Amended Complaint. As S&N notes, moreover, the *Ramirez* decision has been widely criticized by other district courts reviewing allegations of off-label promotion of PMA-approved devices. *See, e.g.*, *Beavers-Gabriel v. Medtronic, Inc.*, 15 F. Supp. 3d 1021, 1035 (D. Haw. 2014) (noting "*Ramirez* has been rejected—for good reason—by numerous courts"). In *Houston v. Medtronic, Inc.* (*Houston II*), for example, the court rejected *Ramirez*'s holding that § 360k(a) does not apply when a manufacturer engages in off-label promotion as inconsistent with the text of the statute, under which preemption turns on whether there are federal requirements applicable to the device, not to a particular use of the device. No. 13-1679, 2014 WL 1364455, at *5 (C.D. Cal. Apr. 2, 2014) (noting "[i]f § 360k(a) does not distinguish between uses of a device, it surely does not distinguish between whether a particular use of a device was promoted by the manufacturer"). The court also found *Ramirez* was inconsistent with "the scope of federal requirements imposed on Class III devices," noting manufacturers of PMA-approved devices are required to report to the FDA information reasonably suggesting a device may have caused or contributed to a death or serious injury, and are prohibited from "making changes in 'design specifications, manufacturing processes, [or the] labeling' of devices without FDA approval, regardless of use." *Id.* (quoting *Riegel*, 552 U.S. at 319). While the court agreed with *Ramirez* that off-label promotion violates federal law, the court viewed the federal prohibition as a possible basis for a parallel claim, rather than a wholesale exemption from preemption. *See id.* at *8. This Court agrees a manufacturer's promotion of off-label uses of a PMA-approved device does not affect whether the device is subject to federal requirements for purposes of § 360a(k). Rather, consistent with *Houston*, the Court will consider Plaintiffs' allegations regarding off-label use as the basis for a potentially nonpreempted parallel claim.

merchantability (Count V),[20] (6) fraud (Count VI), and (7) loss of consortium (Count VII). Plaintiffs acknowledge Count II represents their attempt "to articulate parallel claims," i.e., state-law claims based on violations of federal law, "should the Court find preemption." Oral Arg. Tr. 80, July 16, 2014. S&N argues the Complaint should be dismissed in its entirety because Counts I and III-VI are preempted,[21] Count II fails to state a plausible parallel claim for violations of state common-law duties that parallel the federal requirements applicable to the R3 metal liner, and Count VII is derivative of, and thus cannot survive dismissal of, the remaining counts.

The claims in Plaintiffs' Second Amended Complaint are broad-ranging and extremely general. For their negligence claim, Plaintiffs allege Defendants failed to exercise ordinary care in "the designing, researching, manufacturing, marketing, labeling, supplying, promoting, packaging, sale, testing, quality assurance, quality control, and/or distribution of the R3 Acetabular System, and components such as the R3 metal liner that foreseeably would be used with it." Second Am. Compl. ¶ 119. Plaintiffs' strict liability claim alleges "[t]he R3 Acetabular System, both with and without components such as the R3 metal liner that foreseeably would be used with it," was "defective in design or formulation," *id.* ¶ 141, and that "[t]he R3 Acetabular System and components such as the R3 metal liner that foreseeably would be used with it" were "manufactured defectively" and were defective due to inadequate warnings, instructions, testing, and/or post-marketing surveillance, *see id.* ¶¶ 149, 153-55. The breach of implied warranty claim rests on allegations that Defendants breached implied warranties that "the R3 Acetabular System and components such as the R3 metal liner that foreseeably would be used with it" were

[20] The Second Amended Complaint mistakenly refers to the breach of implied warranties claim, which follows Count IV, as Count VI.

[21] As to Count IV, S&N also argues that insofar as the MDA does not preempt claims for breach of express warranty claims, Plaintiffs have failed to plead a plausible express warranty claim in this case.

"safe and of merchantable quality, and fit for the ordinary purpose for which said product[s] w[ere] to be used." *See id.* ¶¶ 173, 178.

All of these claims unquestionably relate to the safety of the R3 System and the R3 metal liner when used together, and insofar as the claims are directed to the PMA-approved liner, they are expressly preempted by § 360k(a). *See Riegel*, 552 U.S. at 320, 324-25 (holding § 360k(a) preempted state-law claims of "strict liability; breach of implied warranty; and negligence in the design, testing, inspection, distribution, labeling, marketing, and sale" of a PMA-approved device). Although Plaintiffs' claims also purport to challenge the safety of the § 510(k)-cleared R3 System, the body of the Second Amended Complaint reveals that the liner is at the heart of each of Plaintiffs' claims. The Second Amended Complaint identifies the metal-on-metal articulation of the R3 metal liner and the femoral head components of the R3 System as the source of Mr. Shuker's injuries, alleging this articulation was "prone to wearing down and releasing metal debris into the body of the user[,] causing adverse health effects," and also alleging Dr. Terefenko determined Mr. Shuker's pain "was caused by metal sensitivity due to the degeneration of the metal on metal articulation." Second Am. Compl. ¶¶ 98, 111; *see also id.* ¶¶ 95, 105, 120(t), 120(x), 183. Moreover, the Second Amended Complaint identifies the metal liner—not the femoral components—as the source of the problem, alleging Defendants ultimately withdrew the liner "within the R3 Acetabular System" because it was not performing satisfactorily within that System,[22] *see* Second Am. Compl. ¶ 100, and that regulatory authorities

[22] It is not clear whether the recall covered the liner when used within the PMA-approved BHR System. *See* Pls.' Summ. J. Ex. B (FDA's subpoena response characterizing the June 2012 withdrawal of "metal liners of the R3 acetabular system" as "a recall for components sold outside the US," and stating "[t]here was never a US recall from Smith and Nephew in June 2012); S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. C (stating, as part of a S&N "Information and FAQs for Health Care Professionals," that BHR hip implants are not affected by the recall of the R3 metal liner, but also suggesting that, following the recall, "[s]urgeons who

in the United Kingdom advised surgeons to stop using the metal liner because of its unacceptably high revision rate, *see id.* ¶ 102. Dr. Terefenko's operative report for Mr. Shuker's July 2011 revision surgery confirms that Dr. Terefenko identified the metal liner as the "primary generator of the metallic debris." Pls.' Summ. J. Ex. D at 4.

The only factual allegation in the Second Amended Complaint pertaining to the R3 System, as opposed to the liner, concerns the adequacy of the warnings accompanying the System. Plaintiffs allege that while the literature accompanying the BHR System warned surgeons that "when performing a hip resurfacing procedure, the R3 acetabular shell must be used only with an R3 metal liner and the BHR femoral head," Defendants "failed to provide the reverse admonition for the R3 Acetabular System; namely, when performing a hip replacement with the R3 Acetabular System's femoral components, do not mate them with the R3 metal liner." *Id.* ¶ 40 (emphasis omitted); *see also id.* ¶ 129(q), (s) (noting the individual components of the R3 System "do not provide warnings to not use these device components with the R3 metal liner leading users to believe it is safe"). A warning against using the R3 metal liner with the R3 System in a hip replacement procedure is undoubtedly a warning that "relates to the safety or effectiveness" of the liner, regardless of whether the warning accompanies the liner or another component. Allowing Plaintiffs to pursue a claim that the components of the R3 System should have included such a warning would thus effectively impose a state-law requirement "with respect to" the liner that is "different from, or in addition to," the warnings the FDA required. The Court therefore concludes such a claim is no different, for preemption purposes, than a claim challenging the warnings accompanying the liner itself. Because the undisputed facts show Plaintiffs' negligence, strict liability, and breach of implied warranty claims are

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had been using a BHR femoral component with an R3 metal liner can immediately switch to the BHR acetabular component").

preempted, judgment will be entered for S&N as to those claims (Counts I, III, and V). *See Simon*, 18 F. Supp. 3d at 428-429 (holding strict liability, negligence, and breach of implied warranty claims were preempted by § 360k(a) where the plaintiff alleged her injuries "were caused by the 'metal-on-metal' interaction between the metal liner component and the R3 Acetabular System's femoral head component," such that the gravamen of the plaintiff's complaint was "that her injuries were caused by the [PMA-approved] metal liner"); *cf. Bertini*, 8 F. Supp. 3d at 256-57 (holding a claim based on S&N's failure to warn that the R3 System's locking mechanism would not properly secure an R3 metal liner to the R3 shell was preempted because the "interaction between the R3 metal liner and the R3 locking mechanism ma[de] it impossible for plaintiffs to plead sufficient facts showing that the R3 locking mechanism, on its own, caused their injuries").

The MDA does not preempt claims for breach of express warranty as express warranties "do not independently arise by operation of state law" and claims for breach of such warranties thus "do[] not involve . . . state 'requirement[s].'" *Bentzley v. Medtronic, Inc.*, 827 F. Supp. 2d 443, 454-55 (E.D. Pa. 2011); *accord Starks v. Coloplast Corp.*, No. 13-3872, 2014 WL 617130, at *6 (E.D. Pa. Feb. 18, 2014). Under Pennsylvania law, "[a]ny affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." 13 Pa. Cons. Stat. § 2313. Because express warranties are specifically negotiated, "to create an express warranty, the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer understands those terms and accepts them." *Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004), *aff'd*, 885 A.2d 982 (Pa. 2005).

The breach of express warranty claim in Plaintiffs' Second Amended Complaint is based on the wholly conclusory allegations that Defendants "expressly warranted that the R3 Acetabular System and components such as the R3 metal liner that foreseeably would be used with it w[ere] safe and/or well accepted by users," Second Am. Compl. ¶ 162, and "w[ere] safe and fit for use for the purposes intended, . . . w[ere] of merchantable quality, . . . did not produce any dangerous side effects, and . . . w[ere] adequately tested and fit for [their] intended use," *id.* ¶ 167. S&N argues this claim is inadequately pleaded. The Court agrees. The Second Amended Complaint does not identify the source of the warranty (i.e., whether it was made in a publication, package insert, or advertising) and does not say how Mr. Shuker or Dr. Terefenko became aware of it, much less how it became the basis of the bargain between Mr. Shuker and S&N. Nor have Plaintiffs adequately described the content of the warranty, beyond agreeing at oral argument they were *not* claiming Defendants expressly warranted that the R3 System was safe for use in conjunction with the metal liner. *See* Oral Arg. Tr. 74. Because Plaintiffs have failed to plead facts supporting a plausible inference that an express warranty was created, their claim for breach of express warranty (Count IV) will be dismissed with prejudice pursuant to Rule 12(b)(6). *See Starks*, 2014 WL 617130, at *7 (dismissing a breach of express warranty claim where the plaintiff failed to "plead any details regarding the content of any express warranty, how it was made, that it became the basis of the bargain, or that it was directed to [plaintiff]"); *Dougherty v. C.R. Bard, Inc.*, No. 11-6048, 2012 WL 2940727, at *9 n.15 (E.D. Pa. July 28, 2012) (holding to plead a plausible breach of express warranty claim, a plaintiff must allege such facts as "the specific source of the alleged warranty . . . and the specific statements made"); *Kester v. Zimmer Holdings, Inc.*, No. 10-523, 2010 WL 2696467, at *9-10 (W.D. Pa.

June 16, 2010) (dismissing a breach of express warranty claim based on the allegation that defendants "expressly warranted that [their devices] were safe and well accepted by users").

Plaintiffs' remaining claims—their claim for negligence based on violations of FDA regulations and FDCA provisions and their fraud claim—are premised on Defendants' alleged violations of federal law.[23] As noted, because § 360k(a) preempts only those state requirements with respect to a device that are "different from, or in addition to," the federal requirements applicable to the device, the statute "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations," as "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Riegel*, 552 U.S. at 330; *see also Lohr*, 518 U.S. at 495. While a parallel claim must be based on the manufacturer's violation of federal law in order to avoid express preemption, the claim must not arise "*solely* from the violation of FDCA requirements," lest it be impliedly preempted as an attempt to privately enforce the FDCA. *See Buckman*, 531 U.S. at 352-53 (emphasis added). The claim must still be grounded in a violation of state-law duty. *See id.* To plead a parallel claim successfully, a plaintiff's allegations must meet the plausibility standard articulated by the Supreme Court in *Iqbal* and *Twombly*. *See Bass v. Stryker Corp.*, 669 F.3d 501, 509 (5th Cir. 2012); *Bausch*, 630 F.3d at 558. The plaintiff must plead that the manufacturer failed to comply with federal law and that this failure caused his injury. *See Bass*, 669 F.3d at 512.

In Count II of their Second Amended Complaint, Plaintiffs allege Defendants were negligent in that they breached their duty "to comply with the [FDCA] and the regulations

[23] As discussed below, Plaintiffs' fraud claim is based on allegations that Defendants promoted the sale of the R3 System in combination with the R3 metal liner without disclosing the known risks associated with the combined use of the products. *See* Second Am. Compl. ¶¶ 183-85. Because these allegations relate to off-label promotion, the Court construes Plaintiffs' fraud claim one based on Defendants' violation of federal law.

promulgated pursuant to the Act" by violating a host of statutory and regulatory provisions. *See* Second Am. Compl. ¶¶ 128-29. Although defendants devote twenty pages—approximately one-third of the Second Amended Complaint—to cataloging these alleged violations, they offer no legal support for, or explanation of, most of the theories they seek to advance in their briefing of S&N's motion for summary judgment or their own motion for leave to amend. As a result, the Court is left to parse a lengthy laundry list of FDCA provisions and FDA regulations.

The main parallel claim Plaintiffs seek to pursue is a claim based on Defendants' promotion of the R3 metal liner for use off-label with the R3 System. *See* Pls.' Summ. J. Opp'n 15-16; Pls.' Mot. for Leave to Amend 10. A number of the allegations in Count II are directed to off-label promotion. For example, Plaintiffs allege Defendants were negligent in "[p]roviding false and misleading advertising" regarding the R3 metal liner by referring to the liner as "optional" for the R3 system, thereby "creating the false impression that the R3 [A]cetabular [S]ystem had a metal liner component that could be used safely in hip replacements," in violation of 21 U.S.C. §§ 352(q) and 331(a). Second Am. Compl. ¶ 129(r). Plaintiffs further allege Defendants were negligent in providing false and misleading information regarding unapproved uses of the R3 metal liner in hip replacement procedures, in violation of 21 C.F.R. §§ 99.101 and 99.103. *See id.* ¶ 129(x)-(ee); *see also id.* ¶ 129(gg). Off-label promotion is also the subject of Plaintiffs' fraud claim, which alleges Defendants received notice, "through studies, reports, and/or experience," that the metal-on-metal articulation of the R3 metal liner and the femoral components of the R3 System was capable of producing "deleterious volumes of metallic debris," but nevertheless promoted the sale of the R3 System in combination with the R3 metal liner without disclosing the risks associated with the combined use of the products. *See id.* ¶¶ 183-85.

As S&N acknowledges, and as numerous courts have recognized, off-label promotion can be a basis for a nonpreempted parallel claim in some circumstances, as federal law has generally been interpreted to prohibit off-label promotion, at least when it is false and misleading. *See* Oral Arg. Tr. 44, 48 (agreeing that "in appropriate circumstances an off-label promotion claim could go forward"); *see also, e.g.*, *Carson v. DePuy Spine, Inc.*, 365 F. App'x 812, 815 (9th Cir. 2010) (holding "the marketing and promotion of a Class III device for an unapproved use violates Section 331 of the FDCA"); *Schouest v. Medtronic, Inc.*, 13 F. Supp. 3d 692, 701-02 (S.D. Tex. 2014) (concluding that although federal law "does not expressly . . . ban[] off-label promotion," it does bar such promotion "when it is false or misleading"); *cf. In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 239-40 (3d Cir. 2012) (noting the FDCA "generally prohibits manufacturers from marketing, advertising, or otherwise promoting drugs for . . . unapproved or 'off-label' uses"). The precise contours of such a claim are not clear, as the law in this area is continuing to evolve.[24]

[24] Many courts have held that state-law claims based on a manufacturer's affirmative misrepresentations in the course of promoting a device for off-label use—e.g., claims for fraud, breach of express warranty, and negligent misrepresentation—are neither expressly nor impliedly preempted. *See, e.g.*, *Schouest*, 13 F. Supp. 3d at 703-05; *Houston I*, 957 F. Supp. 2d at 1179-81. As the court in *Schouest* explained, such claims are not expressly preempted because "making false or misleading statements about medical devices is prohibited by federal law," and are not impliedly preempted because they are rooted in "independent state law duties that [the manufacturer] allegedly violated after the initial PMA process." 13 F. Supp. 3d at 703-05. While some courts have suggested claims based on omissions in the course of off-label promotion may also escape preemption, *see, e.g.*, *Eidson v. Medtronic, Inc.* (*Eidson II*), 40 F. Supp. 3d 1202, 1228 (N.D. Cal. 2014) (holding fraudulent and negligent misrepresentation claims challenging, inter alia, a manufacturer's omission of information regarding known dangers associated with the off-label use it was promoting were not preempted); *Riley*, 625 F. Supp. 2d at 783-84 (suggesting a claim that, while engaging in off-label promotion, a manufacturer failed to warn about the off-label use it was promoting might not be preempted), other courts have disagreed, *see, e.g.*, *Schouest*, 13 F. Supp. 3d at 705 (holding a negligent misrepresentation claim was expressly preempted insofar as it was premised on the manufacturer's failure to disclose that the promoted off-label use of the device could cause

The Court need not determine the bounds of a permissible parallel claim based on off-label promotion, however, as Plaintiffs have not pleaded facts supporting a plausible inference that Defendants engaged in off-label promotion of the R3 metal liner that influenced the selection of the liner for use in Mr. Shuker's surgery. While Plaintiffs allege Defendants promoted and advertised the liner as "optional" for use with the R3 System, the only instance of such promotion identified in the Second Amended Complaint is the February 2009 press release in which S&N announced the introduction of "an optional 'metal liner' for the R3 Acetabular System."[25] Second Am. Compl. ¶ 91; *see also* S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A (press release). It is not clear whether the press release amounts to off-label promotion. While the press release describes the metal liner as an "option" for the "R3 Acetabular System, an advanced multi-bearing acetabular cup system used in hip replacement and resurfacing procedures," it discloses that the FDA approved the metal liner "for use with the

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injuries); *Hawkins*, 2014 WL 346622, at *15 (holding a claim for failure to provide adequate warnings during off-label promotion was expressly preempted).

[25] Plaintiffs also allege Defendants engaged in off-label promotion by publishing an R3 Acetabular System brochure that describes the surgical technique for inserting the metal liner with the R3 Acetabular System, even though the FDA never approved the metal liner for use with the R3 System. *See* Second Am. Compl. ¶¶ 60-66. The brochure itself—which is included in Plaintiffs' summary judgment exhibits—belies these allegations. The cover page to the brochure bears the heading, "Poly up to 44 mm heads," a reference to the poly liner that received § 510(k) clearance as part of the R3 System, and the brochure goes on to describe the procedure for inserting only a poly (or XLPE) liner into the R3 acetabular shell. *See* Pls.' Summ. J. Ex. A at 13167-90. Plaintiffs seize on the fact that the page of the brochure focused on "R3 acetabular liner insertion" includes a paragraph setting forth certain procedures to be followed "[b]efore inserting the *R3 acetabular liner*," then specifies further instructions "[f]or *XLPE liner insertion*," arguing the reference to the "R3 acetabular liner" constitutes off-label promotion of the R3 *metal* liner for use with the R3 System. *See id.* at 13175 (emphasis added). This interpretation is not plausible. While it is possible the paragraph regarding the procedures to be followed before inserting the R3 acetabular liner includes information generic to all liners of the R3 System, the brochure nowhere mentions the R3 metal liner, and nothing in it suggests it is directed to anything other than the technique for inserting the R3 shell and poly liner. That the brochure is directed to the poly liner is underscored by the six pages it devotes to cataloging S&N's various poly liner options. *See id.* at 13176-77, 13179-80, 13182-83.

BIRMINGHAM HIP™ Resurfacing . . . System." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. A. The press release does not represent the metal liner was approved for use in hip replacement procedures, but states, with respect to hip replacements, that "[s]ince March 2008, the R3 system has been fitted with cross-linked polyethylene (XLPE) liners for use in total hip replacement cases, and Smith & Nephew this week received FDA approval of its ceramic liner option." *Id.* Nevertheless, even assuming the press release is misleading in referring to the liner as an option for use with the R3 System, which, in the United States, "is a total hip replacement system component," Pls.' Summ. J. Ex. B, the Second Amended Complaint alleges no facts suggesting Dr. Terefenko or Mr. Shuker were even aware of the press release, much less that the representations in the press release led to Dr. Terefenko's use of the metal liner in Mr. Shuker's surgery. Although Plaintiffs cite Dr. Terefenko's surgical notes as "allud[ing] to" Defendants' promotional efforts, the surgical notes indicate only that Dr. Terefenko and Mr. Shuker agreed "a metal-metal articulation [wa]s appropriate" for Mr. Shuker, in light of his "body habitus and his activity level." Second Am. Compl. ¶ 55. The notes say nothing about how Dr. Terefenko came to select *Smith & Nephew* components for Mr. Shuker's surgery. Further, insofar as Plaintiffs seek to pursue a fraud claim based on off-label promotion, they have not pleaded this claim within anywhere near the particularity required by Federal Rule of Civil Procedure 9(b). *See* Fed. R. Civ. P. 9(b) ("In alleging fraud . . . , a party must state with particularity the circumstances constituting fraud."); *Houston I*, 957 F. Supp. 2d at 1180 (dismissing fraud claims based on off-label promotion with leave to amend where the plaintiff failed to allege, inter alia, "to whom [the allegedly fraudulent misrepresentations] were made[,] . . . which parts of the misrepresentations were misleading, and *why* they [we]re false"). Accordingly, Plaintiff's fraud

claim (Count VI) and Count II, insofar as it is based on off-label promotion, will be dismissed. The Court will, however, grant Plaintiffs leave to amend as to these claims.

Plaintiffs also seek to pursue a parallel claim based on Defendants' failure to report adverse events associated with use of the R3 metal liner in hip replacement procedures to the FDA, in violation of 21 U.S.C. § 360i, 21 C.F.R. § 803.50, and other FDA regulations. *See* Second Am. Compl. ¶ 129(f), (m)-(p), (jj). The Fifth and Ninth Circuits have held that state-law failure-to-warn claims based on similar allegations are not preempted. In *Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 770-71 (5th Cir. 2011), the Fifth Circuit held a claim that a device manufacturer violated its duty to warn under Mississippi law by failing to accurately report serious injuries and malfunctions of its device, as required under federal law, was a nonpreempted parallel claim. Likewise, in *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1232-33 (9th Cir. 2013) (en banc), the Ninth Circuit held a claim that a device manufacturer breached a duty to use reasonable care under Arizona negligence law by failing to perform its federal-law duty to warn the FDA of adverse events involving its device was not preempted where Arizona tort law "include[d] a cause of action for failure to warn" and "contemplate[d] a warning to a third party such as the FDA." The Eighth Circuit has taken a different view, holding a claim that a device manufacturer "did not timely file adverse event reports, as required by federal regulations," was "an attempt by private parties to enforce the MDA" and was therefore impliedly preempted under *Buckman*. *In re Medtronic, Inc., Sprint Fidelis Leads Prod. Liab. Litig.*, 623 F.3d 1200, 1205 (8th Cir. 2010).

S&N argues this claim is inadequately pleaded because Plaintiffs do not specify the adverse events Defendants failed to report and do not allege how the reports would have reached Dr. Terefenko and changed his treatment decision. S&N also argues the claim is factually

implausible because Mr. Shuker's surgery occurred only two months after the R3 metal liner was released in the United States, and it is virtually impossible that adverse events could have occurred, been reported to the FDA, and found their way to Dr. Terefenko in sufficient numbers to have affected his treatment decision during this narrow two-month window. As to S&N's factual implausibility argument, it not clear that the February 2009 United States launch date for the R3 metal liner is the appropriate starting point for Defendants' duty to report adverse events. Although the metal liner was not released in the United States until February 2009, it received "approval in Europe for market evaluation in January 2007 and for full launch in December 2007, and it was included on the Australian Register of Therapeutic Goods in January 2007." S&N's Opp'n to Pls.' Mot. for Leave to Amend Ex. C. At oral argument, Plaintiffs argued the reportable adverse events were not limited to experience with the R3 metal liner in the United States, noting the recall of the liner was based on "information globally coming back to Smith & Nephew in the UK." Oral Arg. Tr. 82-83. While S&N maintained "the clock started running again" for purposes of the company's reporting obligations when the liner received premarket approval, *see id.* at 97, the FDA granted premarket approval in November 2008, some six months before Mr. Shuker's April 2009 surgery.

The Court agrees, however, that Plaintiffs have failed to plead sufficient facts to render their claim plausible. Even if Plaintiffs need not "specify" the particular adverse events Defendants allegedly failed to report, there must be some factual basis from which it can plausibly be inferred that such events occurred and that Defendants failed to report them during the six-month window in question. The fact that Defendants recalled the R3 metal liner in June 2012 based on data indicating the liner was not performing satisfactorily within the R3 System supports a plausible inference that Defendants became aware of adverse events involving the

liner prior to June 2012, but there is nothing in the Second Amended Complaint to suggest that Defendants failed to report such events to the FDA at any point, much less prior to Mr. Shuker's surgery in April 2009. *Cf. Stengel*, 704 F.3d at 1227 (allegations that device manufacturer failed to report adverse events to the FDA included the allegation that FDA sent a warning letter to the manufacturer two years after plaintiff became paralyzed, stating the manufacturer had misbranded its device by concealing known risks). Plaintiffs have likewise failed to plead facts supporting a plausible inference that had the undisclosed adverse events been reported to the FDA during the six-month window in question, information about those events would have reached Dr. Terefenko in time to prevent Mr. Shuker's injuries. Plaintiffs allege only that had Defendants properly reported all adverse events, "Defendants or the FDA would have taken corrective action," *see* Second Am. Compl. ¶ 129(m)-(p), but this is precisely the sort of conclusory allegation the Fifth Circuit found "entirely speculative" in *Hughes*. *See* 631 F.3d at 776 n.12 (rejecting plaintiff's theory that had the manufacturer properly reported all adverse events, the FDA would have taken some regulatory action against the device).[26] For these reasons, Plaintiffs' parallel claim based on Defendants failure to report adverse events to the FDA will be dismissed with prejudice.

A number of the allegations in Count II are directed to the labeling for the R3 metal liner and/or the components of the R3 System, which Plaintiffs assert was insufficient to alert physicians and patients to the dangers of using the R3 metal liner with the components of the R3 System in a total hip replacement. *See* Second Am. Compl. ¶ 129(i)-(j), (q), (s)-(v), (hh). Although couched as violations of federal law, these allegations are directed to the FDA-

[26] Plaintiffs' allegations regarding Defendants' failure to investigate and take appropriate corrective action with respect to complaints and returned components suffer from similar deficiencies. *See* Second Am. Compl. ¶ 129(e), (g).

approved labeling for the R3 liner, which Defendants were precluded from changing without prior FDA approval. Any claim based on these allegations is therefore expressly preempted. *See Hughes*, 631 F.3d at 769 (holding state-law claims that "would question the sufficiency of the FDA-approved labeling, warnings, and instructions for [a PMA-approved medical device] or require [the manufacturer] to have included different warnings, labels, or instructions with the device" were expressly preempted); *In re Medtronic, Inc.*, 623 F.3d at 1205 (holding claim that a device manufacturer failed to adequately warn consumers of known defects in its device was preempted by § 360k(a) where plaintiffs "did not allege [the manufacturer] modified or failed to include FDA-approved warnings"); *Horn*, 376 F.3d at 177 & n.22 (holding a claim "premised on the adequacies of the warnings reviewed and approved by the FDA in its PMA approval order" was preempted). Plaintiffs elsewhere allege Defendants violated 21 C.F.R. § 1.21 by issuing "brochures, inserts and other materials at variance with what the FDA approved," but they provide no explanation of any such deviation. *See* Second Am. Compl. ¶ 129(ii).

The remaining allegations in Count II are difficult to categorize and, in many instances, incomprehensible to the Court. For example, Plaintiffs allege Defendants failed to identify, capture, and/or correct the "component discrepancy," in violation of 21 C.F.R. § 820.80, but do not explain what this term, which does not appear in the cited regulation, refers to. *See* Second Am. Compl. ¶ 129(c)-(d). It is not clear whether this allegation is directed to a manufacturing defect or some other problem, and insofar as Plaintiffs seek to assert a claim based on a manufacturing defect, it is not clear what facts support the inference that the R3 metal liner implanted in Mr. Shuker was not manufactured in accordance with federal requirements. While the liner was recalled, Plaintiffs do not plead facts suggesting the recall was associated with a manufacturing problem. *See id.* ¶¶ 100-02 (alleging the recall was based on data indicating the

metal liner was not performing satisfactorily within the R3 System); *cf. Bausch*, 630 F.3d at 559 (holding a plaintiff had pleaded a plausible parallel manufacturing defect claim where the complaint alleged the device was implanted in the plaintiff's body six days after the FDA informed the manufacturer that a device component was "adulterated due to manufacturing methods . . . not in conformity with industry and regulatory standards" and where the implanted device was later recalled). The Court likewise concludes any remaining allegations in Count II are insufficient to state a plausible parallel claim.

Having considered S&N's arguments for summary judgment and/or dismissal as to Plaintiffs' Second Amended Complaint, the Court concludes the claims set forth therein are either preempted (Counts I, III, and V, and Count II insofar as it challenges the FDA-approved labeling for the PMA-approved R3 metal liner) or fail to state a claim upon which relief can be granted (Counts IV and VI, and the balance of Count II). Accordingly, the Second Amended Complaint will be dismissed.[27] The Court will, however, grant Plaintiffs leave to amend as to their claims based on off-label promotion.

An appropriate order follows.

BY THE COURT:

/s/ Juan R. Sánchez
Juan R. Sánchez, J.

[27] The dismissal also extends to Count VII, Plaintiffs' claim for loss of consortium, which is derivative of their other claims.